Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Subacute and Chronic Pain Rules

Rule Number(s): 4731-11-01, 4731-11-14

Date: 3/19/19

Rule Type:

- ☐ New
- x Amended
- ☐ 5-Year Review
- ☐ Rescinded

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

Proposed Rule 4731-11-01(X) and (Y) definitions of board certified hematologists and board certified oncologists.

Proposed Rule 4731-11-14(E)(1) exempts board certified hematologists and board certified oncologists from the prohibition against prescribing dosages in excess of an average of 120 Morphine Equivalent Dose to patients.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   The rules are authorized by Sections 3719.062, 4730.39, 4730.07, 4731.052 and 4731.05 of the Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   No. The rules do not implement a federal requirement.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This question is not applicable.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Ohio is experiencing an opioid epidemic that negatively impacts public health resulting in profound consequences to Ohio's economy and way of life. The state's professional licensing boards take action by rule to help affect change and improve health outcomes. The public purpose for the overall rule package is to establish standards and checkpoints between the physician and patient when prescribing opioids for the treatment of subacute or chronic pain.

   The rules became effective in December 2018. Shortly after that time, the Board became aware of two issues that were causing unintended consequences and delays for patients. First, the Board became aware, through interested parties, that non-terminal cancer patients often had pain which required pain medication that exceeded the 120 MED average daily dose and these patients were experiencing delays getting in to see board-certified pain management specialists and board-certified hospice and palliative care specialists. Exempting board-certified hematologists and oncologists from the prohibition in prescribing in excess of 120MED allows those physicians to provide prescriptions to their non-terminal cancer patients without delay.

   In addition, the Board became aware that the definition of "terminal' was also causing delays for patients. Terminal patients are exempted from the rule and the definition in Section 2133.01, Ohio Revised Code was used. The language in Section 2133.01 requires a second opinion for determining that a patient has a terminal condition. This was resulting in a delay

for these patients in obtaining appropriate pain relief. The proposed definition of terminal condition removes this requirement for a second opinion.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   Outcomes reflecting the impact on subacute and chronic opioid prescribing resulting in benefits for public safety will be measured by OARRS data, public health and law enforcement statistics. The success of the regulations will also be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices and medical facilities regarding the provisions of the rule.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The Board received feedback on the unintended consequences of the rule from various physicians and the Ohio Hospital Association. The Board also consulted with Dr. Mark Hurst of the Department of Mental Health and Addiction Services, Dr. Clint Koenig of the Ohio Department of Health, and Dr. Amol Soin, a pain management physician and member of the Medical Board.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   The input caused the Board to move forward with amendments to a rule that only became effective in December 2018.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   Scientific data and data from OARRS was used in the original development of the rule. The Board did not utilize additional scientific data for these limited amendments.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    The proposed amendments directly address the concerns that were raised.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Medical Board has worked with other healthcare licensing agencies in the original promulgation of the rule and has notified other healthcare licensing agencies of the proposed amendments.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The scope of the impacted business community would be licensees of the Medical Board who are authorized to prescribe controlled substances, including opioids. This includes physicians holding a M.D., D.O., or D.P.M. license and physician assistants who are authorized to prescribe.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The amendments will lessen the adverse impact by allowing board-certified hematologists and oncologists to prescribe higher doses to their cancer patients, when necessary to relieve pain. In addition, the amendments will eliminate the requirement for a second opinion to determine that a patient has a terminal condition.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The State has a compelling interest in promoting safe treatment of pain while avoiding risks of harm to patients. Allowing some additional options for cancer patients and patient with terminal conditions is consistent with this interest.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

17. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    Due process requires the Medical Board to consistently apply its rules regarding controlled substance prescribing such that all prescriber licensees are equally treated.

18. **What resources are available to assist small businesses with compliance of the regulation?**

    Medical board staff members are available by telephone and e-mail to answer questions.